IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO LIMIT TESTIMONY OF PROF. DR. MED. UWE KLINGE

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in support of their motion to limit the testimony of Prof. Dr. med. Uwe Klinge. The cases to which this motion applies are identified in Ex. A to the motion.

BACKGROUND

Dr. Klinge is a former hernia surgeon who, when he practiced in his native Germany, used mesh implants in the surgical repair of abdominal wall hernias. Dr. Klinge has been identified as an expert witness in thirty-one cases pending in Wave 3. He offers general opinions about the design of and alternatives to the various meshes manufactured by Ethicon for the treatment of stress urinary incontinence and pelvic organ prolapse.

Dr. Klinge has prepared two Rule 26 expert reports for the Wave 3 cases in which he has been identified as an expert witness, both of which are identical to the reports he submitted for Wave 1.

The first report, dated November 16, 2015, concerns the PROLENE* Mesh used in mid-urethral slings manufactured by Ethicon for the treatment of stress urinary incontinence,

including the TVT, TVT-O, TVT Secur, TVT Abbrevo, and TVT Exact devices. *See* Ex. B, Rule 26 Expert Report of Prof. Dr. Med. Uwe Klinge (Nov. 16, 2015) ("Klinge SUI Report").

Dr. Klinge's second Rule 26 expert report, dated November 17, 2015, relates to the PROLENE* Soft Mesh found in Gynemesh PS, Prolift, and Prosima, each of which Ethicon manufactured for the treatment of pelvic organ prolapse. *See* Ex. C, Rule 26 Expert Report of Prof. Dr. Med. Uwe Klinge (Nov. 17, 2015) ("Klinge Prolapse Report").

The PROLENE* and PROLENE* Soft meshes are both made of polypropylene treated with antioxidants and share the same chemical structure. But they differ in design. PROLENE* Soft has larger pores, weighs less, and has lower burst strength than PROLENE*. Although Dr. Klinge's opinions regarding PROLENE* and PROLENE* Soft overlap to an extent, the bases underlying his opinions are different, and he has been deposed separately regarding his opinions as to each mesh. Accordingly, this memorandum addresses Dr. Klinge's two expert reports separately, with section I below relating to Dr. Klinge's TVT Report and section II relating to his Prolapse Report. Challenges that apply to both reports follow section II.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1–3 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. The Court Should Exclude Dr. Klinge's Opinions Regarding Alternative Designs to the PROLENE* Mesh Used in Ethicon's SUI Products.

In his SUI Report, Dr. Klinge identifies two alternative designs that, he claims, "would be safer in a woman's pelvic tissues as a treatment for incontinence than some of the design characteristics of the Prolene mesh in TVT." *See* Ex. B, Klinge SUI Report at 36. Those

alternative designs are (1) a device made out of "a mesh product with less material and larger distance between the mesh fibers," such as Ethicon's Ultrapro mesh, which is used in hernia repairs; and (2) a device made of polyvinylidene fluoride ("PVDF") mesh rather than polypropylene. *Id.*

a. Dr. Klinge's Opinion Regarding an Ultrapro Alternative Is Speculative.

Dr. Klinge has no reliable basis to testify that a larger pore mesh like Ultrapro would have been safer and efficacious for use in the treatment of stress urinary incontinence. In his expert report, Dr. Klinge does not cite a single clinical study to prove the safety and efficacy of a mid-urethral sling using Ultrapro or a mesh similar to it. Indeed, in the section of his expert report devoted to safer alternative design, Dr. Klinge states only that "a mesh product with less material and larger distance between the mesh fibers" would be safer than PROLENE*. *Id.* He offers no support for this opinion.

Dr. Klinge acknowledged in deposition that, based on this lack of evidence, he is "not able to predict" whether "in the specific function of a sling the Ultrapro really over the time will work really better or whether it will create some new problems." *See* Ex. D, Klinge 10/5/15 Dep. 92:17–93:4. He admitted in that same deposition that answering this question would require "preclinical tests," an "independent textile analysis," and an examination of "tissue reactions looking at animal explants [and] human explants," all of which "should" provide only "a good idea" about whether Ultrapro in a mid-urethral sling is feasible. *Id.* at 94:10–18. These admissions disqualify his testimony, for they admit that he lacks the support in testing and peer-reviewed studies that Federal Rule of Evidence 702 requires. *See Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999) (test data or relevant literature showing testing by others

required); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 681–82 (S.D. W. Va. 2014) (flawed testing failed to meet peer-reviewed standards).

More problematic than the lack of reliable evidence is the fact that Dr. Klinge himself doubts whether a mesh like Ultrapro would actually work for the treatment of stress urinary incontinence. He has previously testified in this MDL that Ultrapro is not an appropriate alternative design for the treatment of stress urinary incontinence because it "is not sufficient to withstand—or to preserve the big pores—under these conditions of biomechanics as it is required for the use as a sling." *See* Ex. E, Klinge 11/15/13 Dep. 529:12–23.

Even today Dr. Klinge has "concerns" that the pores of Ultrapro collapse "at really small forces," and he candidly admitted that he "wouldn't like to have [Ultrapro] in [his] body." *See* Ex. D, Klinge 10/5/15 Dep. 92:1–3, 93:5–14. Dr. Klinge should not be permitted to testify that a larger pore mesh, such as Ultrapro, was a feasible alternative design when he has admitted such a design could very well impair the utility of a mid-urethral sling.

b. Dr. Klinge's Opinion Regarding a PVDF Alternative Is Speculative.

Dr. Klinge's opinion that Ethicon could and should have employed PVDF mesh when designing its various mid-urethral sling products should be excluded for the same reason. Dr. Klinge is able to identify only one stress urinary incontinence device in the whole world that uses PVDF—Dynamesh—which is manufactured by the same German company (FEG) for which Dr. Klinge is a consultant. *See* Ex. D, Klinge 10/5/15 Dep. 101:2–103:16.

Although Dr. Klinge claims Dynamesh is a feasible alternative design, he acknowledged he does not know whether PVDF mesh is subject to particle loss, nor does he know the "stretching profile" of the device under load. *Id.* at 95:15–24. He has not examined whether PVDF mesh is subject to some of the very same criticisms he levies against PROLENE* Mesh in

Ethicon's stress urinary incontinence devices and, therefore, does not have a reliable basis to testify that PVDF mesh was a feasible alternative design available to Ethicon. Nor can he say whether it would be equally effective for the treatment of stress urinary incontinence.

II. The Court Should Limit Certain of Dr. Klinge's Opinions Regarding PROLENE* Soft Mesh Used in Ethicon's Prolapse Products.

a. The Court Should Exclude Any Testimony From Dr. Klinge Regarding Alternative Designs to PROLENE* Soft.

On page 16 of his Prolapse Report, Dr. Klinge states, "The PVDF product, Dynamesh, is a safer design than Gynemesh PS [i.e., PROLENE* Soft Mesh] for all of the reasons stated above as further established in Muehl's testing." *See* Ex. C, Klinge Prolapse Report at 16. This statement is the first reference to polyvinylidene fluoride, or PVDF, in the report, and Dr. Klinge cites no literature or other reliable, objective data to support it. In fact, the only other references to PVDF—or any other alternative design, for that matter—in Dr. Klinge's entire report are summaries of company documents that, in Dr. Klinge's view, show Ethicon considered PVDF as an alternative to polypropylene, among other possible changes to the design of PROLENE* Soft Mesh. *See* Ex. C, Klinge Prolapse Report at 25–26.

Notably, Dr. Klinge's Prolapse Report is virtually identical to the report he submitted in *Bellew*, where this Court excluded Dr. Klinge's opinions on alternative design. The Court found that, in the section of his *Bellew* report addressing alternative design, "Dr. Klinge fails to cite *any* peer-reviewed studies." Mem. Op. & Order (*Daubert* Motions) at 16, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014) [ECF #265] ("*Bellew* Order"). This Court also emphasized that "Dr. Klinge's report provides no indication that his alternative design opinions are based on anything other than his and Dr. Mühl's effective porosity testing and internal Ethicon documents," which the Court deemed "not sufficiently reliable scientific bases under

Daubert." *Id.* Because Dr. Klinge has submitted the same report here, the Court should again exclude his alternative design opinions.

Plaintiffs here may well argue that a different result is compelled by Dr. Klinge's *de bene esse* deposition in *Bellew*—which occurred after *Daubert* briefing in *Bellew* but before the Court issued its opinion excluding Dr. Klinge's alternative design opinions. Any such argument would be misplaced. Dr. Klinge testified in *Bellew* that he is not aware of any peer-reviewed studies showing PVDF—or any other proposed alternative to PROLENE* Soft—is safer and more effective at treating pelvic organ prolapse. *See* Ex. F, Klinge 11/10/14 Dep. 182:14–184:2 (testifying he is not aware of any clinical studies showing alternative mesh design that has lower rate of erosion, that causes less chronic pain, or that has lower contracture rate than PROLENE* Soft Mesh).

In fact, when Dr. Klinge was asked in that deposition whether he could even identify "any mesh . . . that's appropriate for use in the pelvic floor for the repair of pelvic organ prolapse," Dr. Klinge responded, "I cannot give a general statement to this. I know that there are textile constructions and design for meshes that are more resistant to the [pore] collapse, but it depends on the indication of the specific situation." *Id.* at 163:8–15.

Dr. Klinge later confirmed that he could not name one mesh with usage benefits that exceed the risks of use in the treatment of pelvic organ prolapse. *Id.* at 184:3–6. And he specifically denied that a larger-pore mesh like Ultrapro is a safer alternative to PROLENE* Soft. *Id.* at 90:11–20 ("Ultrapro obviously does not prevent a pore collapse when applied to forces; therefore, it is not the best idea to use Ultrapro in this—for this indication, yes.").

In short, nowhere in his Rule 26 expert report or in his *de bene esse* deposition does Dr. Klinge cite peer-reviewed literature to support his opinion that PVDF or mesh with larger pores

were safer alternatives to PROLENE* Soft. Instead, he relies only on his "effective porosity testing and internal Ethicon documents, which are not sufficiently reliable scientific bases under *Daubert*." *Bellew* Order at 16. As a result, he should not be permitted to testify regarding alternative design in cases involving Ethicon's prolapse products.

b. Dr. Klinge's Opinions Regarding Fraying and Particle Loss in PROLENE* Soft Should Be Excluded.

The Court should also exclude Dr. Klinge's opinion that PROLENE* Soft is defective because it is subject to fraying and particle loss. *See* Ex. C, Klinge Prolapse Report at 19–23. In support of that opinion, Dr. Klinge cites a number of Ethicon documents relating to TVT, a mid-urethral sling used in the treatment of stress urinary incontinence, not pelvic organ prolapse. For example, Dr. Klinge cites a 2003 memorandum to the TVT file indicating that "fraying is inherent in the design and construction of the product," clinical reports from 2004 describing "crumbling" of TVT, and elongation studies comparing the effect of various methods of cutting TVT mesh. *Id.* at 19–20. Dr. Klinge also relies on a 2003 study by Pariente describing "particle shedding" in TVT. *Id.* at 20.

The Ethicon documents and the Pariente study cited by Dr. Klinge provide no support whatsoever for his opinion that PROLENE* Soft Mesh frays and loses particles. *Id.* 19-20. Ethicon uses PROLENE* Mesh in the TVT device described in these documents, not the PROLENE* Soft Mesh found in Prolift and Ethicon's other pelvic organ prolapse products. As mentioned, PROLENE* and PROLENE* Soft have different designs, including different pore sizes and different weights (PROLENE* Soft has larger pores and weighs less). Thus, even if internal company documents were somehow a reliable basis to show mesh fraying and particle loss in PROLENE*, these internal documents cannot reliably support Dr. Klinge's opinion that

PROLENE* Soft Mesh frays and loses particles, insofar as the documents relate to an entirely different product.

Stripped of the TVT documents, the only "data" Dr. Klinge cites in support of his opinion that PROLENE* Soft Mesh frays and loses particles is his observation of "curled and roped mesh . . . in the Prolift implantation videos" he was provided. *See* Ex. C, Klinge Prolapse Report at 23. In his *de bene esse* deposition for *Bellew*, Dr. Klinge referenced this same video, again identifying it as proof of roped and curled mesh. *See* Ex. F, Klinge 11/10/14 Dep. 73:7–75:18. Nowhere in his report or in his deposition, however, does Dr. Klinge explain how mesh roping or curling allegedly seen in this video is related to his claim that PROLENE* Soft Mesh frays and loses particles. Without a reliable basis to support his opinion that fraying and particle loss occur, Dr. Klinge should not be permitted to testify about this supposed defect.

III. Dr. Klinge's Narrative Summary of Ethicon Documents and Depositions and His Opinions Concerning Ethicon's Knowledge, State of Mind, and Corporate Conduct Should Be Excluded.

Both of Dr. Klinge's expert reports are replete with opinions regarding Ethicon's alleged knowledge of a variety of topics and narrative summaries of Ethicon's documents. *See*, *e.g.*, Ex. B, Klinge SUI Report at 9 ("Ethicon employees have testified that Ethicon knew before the launch of its pelvic meshes . . . that in some women, there would be a severe FBR . . . ."); *id.* at 14 ("Numerous Ethicon internal documents demonstrate Ethicon was acutely aware of the heavyweight, small pore problem."); Ex. C, Klinge Prolapse Report at 29 ("According to their documents, Ethicon also acknowledged why these design requirements were so important in terms of patient safety."); *id.* (". . . Ethicon knew that poor design leads to poor outcome."). This Court ruled in *Lewis* that Dr. Klinge's opinions regarding Ethicon's documents and corporate knowledge "are not appropriate subjects of expert testimony because opinions on these matters

will not assist the jury." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *5 (S.D. W. Va. Jan. 15, 2014).

In the *Bellew* case, Dr. Klinge included in his report the same improper opinions regarding Ethicon's knowledge and state of mind. In response to Ethicon's *Daubert* motion, the plaintiff insisted she did not intend to elicit such testimony from Dr. Klinge, and the Court denied as moot Ethicon's motion on this point. *Bellew* Order at 14-15.

Yet, during Dr. Klinge's *de bene esse* deposition for *Bellew*, the plaintiff's counsel elicited the very testimony Ethicon had moved to exclude. *See, e.g.*, Ex. F, Klinge 11/10/14 Dep. 65:23–66:4 ("Q. Okay. In your review of the internal Ethicon documents in this case, did you determine whether Ethicon's scientists had considered your and Dr. Mühl's pore testing publications and the effects of mesh pore size under strain? A. Yes I did."); *id.* at 67:7–10 ("They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it."). Counsel for the plaintiffs elicited the same type of testimony in Dr. Klinge's *de bene esse* deposition for the *Mullins* consolidated case. *See, e.g.*, Ex. G, Klinge 11/4/15 Dep. 24:1–18 (testifying that "internal Ethicon document" "clearly expressed that . . . the Ethicon scientists still recognized the importance of, first, large pore sizes and, second, minimal amount of foreign body material as recommendations for a mesh construction.").

As this Court has already recognized, Dr. Klinge's opinions about Ethicon's knowledge and corporate conduct should be excluded. These opinions would not be helpful to the jury, *see Lewis*, 2014 WL 186872, at *6, and they "would actually invade the province of the jury rather than assist it in resolving material issues of fact," as Dr. Klinge's opinions are predicated on nothing more than his own reading of Ethicon's documents. *See Hines v. Wyeth*, No. 2:04-0690,

2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011).

CONCLUSION

For the reasons set forth above, certain of Dr. Klinge's opinions fail to pass muster under *Daubert*, and the Court should limit his testimony at trial.

Respectfully submitted,

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1800
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON

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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON